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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,451	03/09/2004	Adnan Badwan	85943.8276	2422

22242 7590 11/17/2008
FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
MAHYERA, TRISTAN J	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/796,451	BADWAN ET AL.	
	Examiner	Art Unit	
	TRISTAN J. MAHYERA	1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 October 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's amendment to Claim 1, specifically the introduction of "non-hydroscopic" raises new issues that require further consideration and further search because the additional limitation, while better defining the scope of the invention will require a through search of the prior art. The arguments below address the claims without the additional amendments. The amendment to distinctly differentiate between the therapeutic agents and the organic acids, specifically "additional", while again clarifiying the invention, will require a search for "additional orgainic acids" with the therapeutic agent.

Response to 112 arguments:
Because the amendments to claim 1 will not be entered the 112 rejection is maintained.

Response to 103 arguments:
Applicants argue that the ANZAGHI reference would not be chosen because of the requirement for an adduct formed with a polysaccharide polymer, which is not disclosed in the claimed invention. This is not found persuasive because instant claim 1 uses the term "containing", which is read as "comprising" and does not limit the use of additional elements such as the said polymer. As stated in the office action ANZAGHI contains the quinolonic antibacterial agents, specifically norfloxacin and thus would be a highly valuable reference used by a person skilled in the art.

Applicants argue that the STROM reference does not contain any teaching or suggestion for combination with the ANZAGHI reference because STROM teaches amoxicillin in a bilayer tablet. This is not found persusave because the bilayer tablet is not expliciitly excluded from the instant claims, nor would such a layered tablet in any manner interfere with the non-hygroscopic compositions of the instant invention. While the STROM reference uses amoxicillin, which is water soluble, it is also an antibacterial agent that uses sodium starch glycolate and anhydrous citric acid as a release retarding agent that would be used by a person skilled in that art to control the release of any antibacterial agent, not specifically amoxicillin. The reason for combining STROM and ANZAGHI does not have to be the reason for using the excipients in the instant invention, however, the stabilizing effect of citric acid is an inherent quality of the acid inseparable from its structure. As stated in the office action the citric acid is combined to control or retard the release of the antibacterial agent, thus the amount used would be a matter well within the scope of a person skilled in the art, e.g. a greater amount of citric acid would further retard the release further obviating the percent used in the instant invention.

Applicants argue that the KATDARE reference is combined by hindsight analysis and the use of wet granulation renders the combination improper because amoxiciliin from the STROM reference is highly water soluble. The instant claims are product/compositon claims thus the use of wet granulation is not given any patentable weight because it does not add any structural limitation, thus the argument is rendered moot as any method can be used to achieve the final product/composition. Regarding the use of hindsight analysis: The Examiner is unclear exactly what Applicant was arguing regarding the use of a slow-release composition in STROM, because Applicant does not limit the instant invention to either a slow/fast or controlled release composition. However, the KATDARE patent teaches film coatings such as HPC and HPMC, which are well known to give controlled or retarded release properties to a dosage form, thus a person skilled in the art would be motivated to look at both STROM and KATDARE without hindsight analysis.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615